DEC - 5 2000

K003141
Page 1 of 4

PARADIGM MEDICAL INDUSTRIES INC.,

2355 South 1070 West
Salt Lake City, Utah 84119
(801) 977-8970
(801) 977-9043 (fax)
Tracy S. Best, Manager, Regulatory Affairs & Quality Assurance

Preparation Date: 10/09/00

Summary of Safety and Effectiveness for the:

Trade Name: UBM Plus, Model P45

Common Name: Ultrasound Echo Imaging System

Classification Name: **System, Imaging, Pulsed Echo, Ultrasonic**

Legally Marketed Predicate Devices for Substantial Equivalence:

* K923348, A/B Scan, Model 835 - Humphrey Instruments

* K923211A, Ophthalmic Ultrasound BioMicroscope, Model UBM - Humphrey Instruments

Rationale for SE: The aforementioned devices share similar indications for use, and identical design features including; chassis, PCBA's, power supplies, etc. Control systems such as footswitch, trackball, and thermal graphic printer including displays are available for user intervention. Functional features such as; A-Scan, A-Diagnostic, B-Scan and Ultrasonic BioMicroscope are also identical to the aforementioned devices. *Also see Attachment "A"* Comparison Chart of Equivalence.

Description of Submitted Device:

The UBM *Plus* an instrument used in the application of Diagnostic Ophthalmology Echo Imagery and produces an image by a pulsed sound beam technology that determines the depth of tissues within the eye. The image captured from the interpreted signal is then displayed on the monitor supplied with the device. With an integrated transducer and frequencies of 8, 10, and 50 MHz, the UBM *Plus* is the ideal instrument for diagnostician in Ophthalmology.

Intended Uses of the Elite Family Lasers:

See attachment "B" for a complete listing of indicated uses (applied for).

Technological Characteristics and Substantial Equivalence:

The UBM from Humphrey Instruments was cleared under the 510(k) number K923211A utilizing the equivalent 50 MHz transducer probe suspended on a gantry arm. The UBM is able to display a quality two-dimensional image of the Anterior Segment of the eye for the detection and evaluation of anterior segment tumors, anterior angle glaucoma as well as other structures of the anterior chamber. This technology has remained basically unchanged since the initial release by Humphrey Instruments.

The A/B Scan from Humphrey Instruments was cleared under the 510(k) number K983348. The initial release of this product was the Model 835. Humphrey Instruments later added the ability to utilize a Diagnostic A Probe that produces A-Scan images with a specific signal processing for diagnostic capabilities, having a transducer frequency of 8 MHz. Since this change was documented under their quality system, and it was similar to the A-Scan Probe of 10 MHz. A letter to file documenting the change, including renaming it to the 837, and therefore, Humphrey Instruments did not file a new 510(k).

Paradigm Medical Industries acquired the rights to these products in 1998 and has manufactured them since. The UBM *Plus*, Model P45 is the combination of the two products mentioned above. The Humphrey Model 840 is the Paradigm Model P40. The Humphrey Model 837 is the Paradigm Model P37. By combining the technologies of these two devices on the same chassis, and incorporating the same power supply, PCBA's, and similar software, etc., we feel that the UBM *Plus*, Model P45 is substantially equivalent to the aforementioned devices. Because of the simplicity of the creation of the new model, a "Special (30-day) 510(k)" is warranted.

Conclusion:

The UBM *Plus*, Model P45 is substantially equivalent to products already on the market and approved for use in Ophthalmology. By incorporating the proven safety and effectiveness of these two devices into one, the P45 is equally safe and effective.

From Attachment A

Comparison Table of Ultrasound Devices

	Paradigm Medical UBM *Plus*, Model P45	Humphrey Instruments Digital Ophthalmic UBM	Humphrey Instruments A/B Scan, Model 835
Transducer(s) and Power	A-Scan, 10 MHz Diagnostic A, 8 MHz B-Scan, 10 MHz Ultrasonic BioMicroscope, 50 MHz	Ultrasonic BioMicroscope, 50 MHz	A-Scan, 10 MHz Diagnostic A, 8 MHz B-Scan, 10 MHz
Cooling System	Forced Air Cooling, Dual fan system	Forced Air Cooling, Dual fan system	Forced Air Cooling
Scan Characteristics	Scan Rate of 8 Hz (13 or 18 MHz B-Scan) Sampling Resolution of 5µ*m* Scan Width 5mm (UBM) Scan Depth 5mm (UBM) 0-60mm (others) Scan Angle (B-Scan) 40° & 60° Selectable	Scan Rate of 8 Hz Sampling Resolution of 5µ*m* Scan Width 5mm Scan Depth 5mm	13 or 18 MHz B-Scan Sampling Resolution of 5µ*m* Scan Angle (B-Scan) 40° & 60°, Selectable Scan Depth 0-60mm
Electrical Specifications	110 V~ or 220 V~ 50/60 Hz, 750 VA	110 V~ or 220 V~ 50/60 Hz, 750 VA	110 V~ or 220 V~ 50/60 Hz, 750 VA
Display Monitor	15 inch Color CRT, Custom Display	15 inch Color CRT, Custom Display	15 inch Color CRT, Custom Display
System Control Input Devices	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port	3 button trackball/thumbwheel control Dual position 'IPX1' rated footpedal Light Pen - alphanumerics entry SCSI port
Image Storage	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive	High capacity Hard Disk, 1.2 GB 1.44 MG 3.5 Inch floppy disk drive
Dimensions/Wt.	15.25" X 18.25" X 7.13" 40 lbs.	15.25" X 18.25" X 7.13" 40 lbs.	15.25" X 18.25" X 7.13" 40 lbs.
510(k) Number	Pending this application	K923211A	K923348

From Attachment B

K003141
Page 4 of 4

510(k) Number (if known): _____

Device Name: UBM *Plus*, Model P45

Indications For Use:

√ Ultrasound imaging of the eye
√ Produce axial measurements of the eye
√ Imaging the intraocular anatomy and pathology of the eye
√ Imaging the anterior segment of the eye
√ Imaging the anterior angle for Glaucoma Management
√ Imaging of other structures of the anterior chamber
√ Acquire and view real-time high resolution images of the anterior segment under magnification that produces a multi-dimensional view of the eye for diagnostic evaluation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Ms. Tracy S. Best
Manager, Regulatory Affairs
and Quality Assurance
Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119

Re: K003141
P45 UBM Plus
Regulatory Class: II
21 CFR §892.1560
Product Code: 90 IYO
Dated: November 9, 2000
Received: November 14, 2000

Dear Ms. Best:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the P45 UBM Plus, as described in your premarket notification:

Transducer Model Number

A-Scan 10 MHz
A-Diagnostic 8 MHz
B-Scan 10 MHz
Biomicroscope 50 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: P45 UBM *Plus*
Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

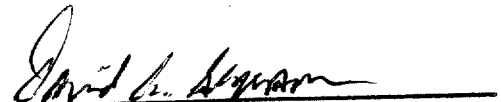
Clinical Application		Mode of Operation					
General (Track I Only)	Specific (Tracks I & III)	B-Scan	PWD	CWD	A-Scan	A-Diagnostic	Other* (Specify)
Ophthalmic	Ophthalmic	N			N	N	
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric						
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Conventional)						
	Musculo-skel. (Superficial)						
	Intra-luminal						
	Other (Specify)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esoph. (Cardiac)						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel						
	Other (Specify)						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003141

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System:
Transducer: A-Scan *10 MHz*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track I Only)	Specific (Tracks I & III)	B-Scan	PWD	CWD	A-Scan	A-Diagnostic	Other* (Specify)
Ophthalmic	Ophthalmic				N		
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric						
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Conventional)						
	Musculo-skel. (Superficial)						
	Intra-luminal						
	Other (Specify)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esoph. (Cardiac)						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel						
	Other (Specify)						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K003141

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System:
Transducer: A-Diagnostic 8 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track I Only)	Specific (Tracks I & III)	B-Scan	PWD	CWD	A-Scan	A-Diagnostic	Other* (Specify)
Ophthalmic	Ophthalmic					N	
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric						
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Conventional)						
	Musculo-skel. (Superficial)						
	Intra-luminal						
	Other (Specify)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esoph. (Cardiac)						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel						
	Other (Specify)						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003141

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System:
Transducer: B-Scan 10 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track I Only)	Specific (Tracks I & III)	B-Scan	PWD	CWD	A-Scan	A-Diagnostic	Other* (Specify)
Ophthalmic	Ophthalmic	N					
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric						
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Conventional)						
	Musculo-skel. (Superficial)						
	Intra-luminal						
	Other (Specify)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esoph. (Cardiac)						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel						
	Other (Specify)						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003141

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System:
Transducer: Biomicroscope 50 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track I Only)	Specific (Tracks I & III)	B-Scan	PWD	CWD	A-Scan	A-Diagnostic	Other* (Specify)
Ophthalmic	Ophthalmic	N					
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric						
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Conventional)						
	Musculo-skel. (Superficial)						
	Intra-luminal						
	Other (Specify)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esoph. (Cardiac)						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel						
	Other (Specify)						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003141

Prescription Use (Per 21 CFR 801.109)